



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader
January 8, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

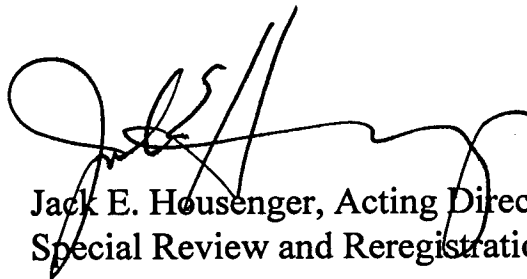
The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director
Special Review and Reregistration Division

282

December 2, 1997

MEMORANDUM

SUBJECT: Oxydemeton-methyl: **Product and Residue Chemistry Chapters for the Reregistration Eligibility Decision (RED) Document.**

DP Barcode: D235189

Chemical No.: 058702

Reregistration Case No.: 0258

FROM: Paula A. Deschamp, Biologist
Reregistration Branch 2
Health Effects Division [7509C]

THRU: Alan P. Nielsen, Senior Scientist
Reregistration Branch 2
Health Effects Division [7509C]

TO: Cathy Monk, Branch Chief/Mary Begley, CRM
Reregistration Section 2
Reregistration Branch
Special Review and Reregistration Division [7508W]

Attached are the Product and Residue Chemistry Chapters to the HED Oxydemeton-methyl RED. The chapters were assembled by Dynamac Corporation under supervision of HED. The data assessment has undergone secondary review by the HED Chemistry Science Advisory Council and has been revised to reflect Agency policies.

Product Chemistry

Some data requirements remain outstanding for the technical registrant of oxydemeton-methyl.. These data gaps should not impinge upon the reregistration eligibility decision.

Residue Chemistry

The existing data base for oxydemeton-methyl is substantially complete. Storage stability data are required for processed commodities and livestock commodities. In addition, the sample storage intervals and conditions for all residue data submitted in support of tolerances must be supplied. Sufficient magnitude of residue data have been submitted to reassess most tolerances, but studies remain outstanding for sweet corn (K+CWHR), sweet corn stover, grain sorghum stover, cotton gin by-products, alfalfa forage, hay and seed. A worst-case risk assessment may still be conducted using the reassessed tolerances despite the lack of data.

Attachments 1 and 2

cc: (with attachments): PDeschamp (RRB2), Circulate, Reg Std File, SF, M. Begley (SRRD)
7509C:RRB2:PDeschamp:pad:CM#2:Rm 718K:703-305-6227:12/2/97

Attachment 1

OXYDEMETHON-METHYL

REREGISTRATION ELIGIBILITY DECISION:

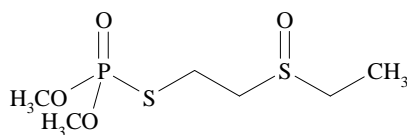
PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 058702; Case No. 0258

(CBRS No. 17875; DP Barcode D235189)

DESCRIPTION OF CHEMICAL

Oxydemeton-methyl (S-[2-(ethylsulfinyl)-ethyl] O,O-dimethyl phosphorothioate) is a phosphorothioate, organophosphorous pesticide which is registered for use as a systemic acaricide and insecticide on a variety of food and non-food use sites.



Empirical Formula:	C ₆ H ₁₅ O ₄ PS ₂
Molecular Weight:	246.3
CAS Registry No.:	301-12-2
Shaughnessy No.:	058702

IDENTIFICATION OF ACTIVE INGREDIENT

Oxydemeton-methyl is a colorless to amber-colored liquid with a boiling point of 106 C. Oxydemeton-methyl is miscible with water; readily soluble (10-100 g/100 mL) in dichloromethane, 2-propanol, and toluene; and practically insoluble (<1 g/100 mL) in n-hexane.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/27/97 identified a single oxydemeton-methyl manufacturing-use product (MP) registered under Shaughnessy No. 058702: the Gowan Company 50% FI (EPA Reg. No. 10163-219). We note that the Gowan 50% FI was transferred from Mobay Corporation (EPA Reg. No. 3125-99). Because the oxydemeton-methyl PAI and TGAI are not stable, oxydemeton-methyl is diluted with solvent to form the 50% FI. Only the Gowan MP and its unregistered TGAI are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Oxydemeton-Methyl Guidance Document dated 9/87 required that updated product chemistry data be submitted for the oxydemeton-methyl MPs. The Oxydemeton-Methyl Reregistration Standard Update dated 1/17/92 reviewed data submitted in response to the Guidance Document and summarized the product chemistry database in support of the reregistration of oxydemeton-methyl. The Update required additional product chemistry data concerning almost all GLNs for the Mobay Corporation oxydemeton-methyl 50% FI.

Upon petition by Gowan Company, the Greybeard Committee (1/93) waived certain requirements for product chemistry data specified in the Oxydemeton-Methyl Update (CBRS No. 15332, D213718, 3/20/97, S. Funk). The committee determined that data for the MP could be translated or extrapolated to the unstable TGAI for GLNs 61-3 and 62-1 (OPPTS 830.1670 and 830.1700), and waived requirements for additional data for GLNs 61-1, 62-2, 63-8, and 63-13, and 63-16 (OPPTS 830.1550, 830.1750, 830.7840-60, 830.6313, and 830.6316).

The current status of the product chemistry data requirements for the oxydemeton-methyl MP is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent data requirements are satisfied for the Gowan 50% FI, except for a new data requirement (OPPTS 830.7050) concerning UV/visible absorption of the PAI. Provided that the registrant submits the data required in the attached data summary table for the 50% FI, and either certifies that the suppliers of beginning materials and the manufacturing process for the oxydemeton-methyl MP have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of oxydemeton-methyl with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 15332
DP Barcode(s): D213718
Subject: Oxydemeton-Methyl (List A, Chemical 058702, Case 0258). Gowan Company Product Chemistry: GLN's 61, 62, 63 Series (OPPTS Test Guidelines 830 Series).
From: S. Funk
To: P. Deschamp
Dated: 3/20/97
MRID(s): 42951201-42951203

PRODUCT CHEMISTRY CITATIONS: Bibliographic citations include only MRIDs containing data which fulfill data requirements. References (cited):

40202601 Talbott, T. (1987) Product Chemistry of Metasystox-R 50% Concentrate. Unpublished compilation prepared by Mobay Corp. 68 p.

40202602 Talbott, T. (1987) Product Chemistry of Dylox/Metasystox-R 1.5-0.5 for Use Only in Repacking of an Insecticide. Unpublished compilation prepared by Mobay Corp. 93 p.

40202603 Talbott, T. (1987) Product Chemistry of Metasystox-R 2 Spray Concentrate Systemic Insecticide and Systemic Spray Insecticide Contains Metasystox-R. Unpublished compilation prepared by Mobay Corp. 68 p.

40501901 Hellbusch (1983) Octanol Water Partition Coefficient of Oxydemeton-methyl Pure Active Ingredient: 75740/1983. Unpublished Mobay study no. 94657 prepared by Bayer AG. 7 p.

40620301 Talbott, T. (1988) Product Chemistry of Metasystox-R Technical: AD No. 605131: AD No. 201226. Unpublished study prepared by Mobay Corp. 28 p.

40784901 Talbott, T. (1988) Product Chemistry of Metasystox-R Technical: BR 1610. Unpublished compilation prepared by Mobay Corp. 55 p.

40784902 Sewekow (1980) Vapor Pressure of Oxydemeton-methyl Pure Active Ingredient: Study No. AP 680 825. Unpublished study prepared by Bayer AG. 6 p.

40784903 Krohn, J. (1987) Water Solubility of Oxydemeton-methyl Pure Active Ingredient. Unpublished study prepared by Mayer AG in cooperation with Bayer AG. 5 p.

40877101 Talbott, T. (1988) Product Chemistry of Metasystox-R Technical: Mobay Report 98340. Unpublished study prepared by Mobay Corp. 11 p.

42951201 Fontaine, L. (1993) Supplement to MRID 40620301: Product Chemistry of Oxydemeton-methyl and Metasystox-R 50%: Lab Project Number: AD.21115: AD.101103: AD.201226. Unpublished study prepared by Miles Inc. 48 p.

42951202 Fontaine, L. (1993) Supplement to MRID 40202601; Product Chemistry of Oxydemeton-methyl and Metasystox-R 50%: Lab Project Number: 94374: TM C-11.22. Unpublished study prepared by Miles Inc. 25 p.

42951203 Fontaine, L. (1993) Supplement to MRID 40784901: Product Chemistry of Oxydemeton-methyl and Metasystox-R 50% Concentrate: Lab Project Number: 86831: 91367: 106263. Unpublished study prepared by Miles Inc. 34 p.

Case No. 0258
Chemical No. 058702

Case Name: Oxydemeton-methyl
Registrant: Gowan Company
Product(s): 50% FI (EPA Reg. No. 10163-219)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product Identity and Disclosure of Ingredients	Y ³	40620301
830.1600 830.1620 830.1650	Starting Materials and Manufacturing Process	Y	40620301 , 42951201
830.1670	Discussion of Formation of Impurities	Y ³	40620301 , 42951201
830.1700	Preliminary Analysis	Y ³	40202601, 40202602, 40202603, 40877101, 42951202
830.1750	Certification of Ingredient Limits	Y ³	40202601, 40877101
830.1800	Analytical Methods to Verify the Certified Limits	Y	40202601, 40877101 , 42951202
830.6302	Color	Y	40784901
830.6303	Physical State	Y	40784901
830.6304	Odor	Y	40784901 , 42951203
830.6313	Stability	Y ³	40784901
830.6314	Oxidation/Reduction	Y	40784901 , 42951203
830.6315	Flammability	Y	40784901 , 42951203
830.6316	Explodability	Y ³	40784901
830.6317	Storage Stability	Y	40784901 , 42951202, 42951203
830.6319	Miscibility	N/A ⁴	40784901
830.6320	Corrosion Characteristics	Y	40784901 , 42951203
830.7000	pH	Y	40784901 , 42951203
830.7050	UV/Visible Absorption	N ⁵	
830.7100	Viscosity	Y	40784901 , 42951203
830.7200	Melting Point/Melting Range	N/A ⁶	
830.7220	Boiling Point/Boiling Range	Y	40784901 , 42951203
830.7300	Density/Relative Density/Bulk Density	Y	40784901 , 42951203
830.7370	Dissociation Constant in Water	Y	40784901 , 42951203

830.7550	Partition Coefficient (Octanol/Water)	Y	40501901, 40784901
830.7560			
830.7570			
830.7840	Solubility	Y ³	40784901, 40784903
830.7860			
830.7950	Vapor Pressure	Y	40784901, 40784902, 42951203

¹ Y = Yes; N = No; N/A = Not Applicable.

² **Bolded** references were reviewed in the Oxydemeton-methyl Reregistration Standard Update dated 1/17/92, and all other references were reviewed under CBRS No. 15332, D213718, 3/20/97, S. Funk.

³ The Greybeard committee waived requirements (1/93) for additional data specified in the Oxydemeton-Methyl Update (CBRS No. 15332, D213718, 3/20/97, S. Funk).

⁴ Data are not required because the MP is not oil based or diluted with oil.

⁵ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

⁶ Data are not required because the TGAI is a liquid at room temperature.

Attachment 2

OXYDEMETON-METHYL

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 058702; Case 0258

(CBRS No. 17875; DP Barcode D235189)

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OXYDEMETON-METHYL

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 058702; Case 0258

INTRODUCTION

Oxydemeton-methyl (S-[2-(ethylsulfinyl)ethyl] O,O-dimethyl phosphorothioate) is an acaricide and insecticide registered by Gowan Company under the trade name Metasystox®-R. Oxydemeton-methyl (ODM) is currently registered for multiple foliar applications on beans (lima), broccoli, broccoli raab (CA950002), Brussels sprouts, cabbage, cauliflower, corn (sweet), cotton, cucumbers, eggplant, grapefruit, lemons, lettuce (head), melons (including muskmelons), oranges (FL960006), peppermint, peppers, pumpkins, spearmint, squash (summer and winter), strawberries, sugar beets, walnuts, and watermelons. ODM is also registered for bark treatment on filberts, for treatment of nonbearing apples, apricots, cherries, crabapples, grapes, nectarines, peaches, plums/prunes, and quinces, and for treatment of alfalfa and clover seed crops. In general, applications may be made with either ground or aerial equipment. The 2 lb/gal emulsifiable concentrate (EC) formulation is the only ODM formulation class registered for use on food/feed crops.

REGULATORY BACKGROUND

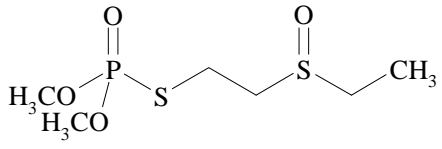
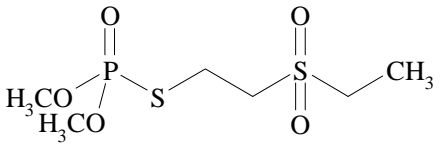
Oxydemeton-methyl is a List A FIFRA reregistration chemical and was the subject of a Reregistration Standard Guidance Document dated 9/87. The Residue Chemistry Chapter of the Guidance Document was completed on 11/7/86. The Residue Chemistry Chapter Update of the Oxydemeton-Methyl Reregistration Standard was issued on 6/17/92. These documents summarized the regulatory conclusions based on available residue chemistry data, and specified the additional data required for registration purposes. All data submissions received since the ODM Update have been reviewed and evaluated. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of ODM.

A Special Review of ODM was initiated in 1987 (PD 1, Federal Register Vol. 52, pg.192, 10/5/87) due to concerns over reproductive effects and worker exposure. At the time the Special Review was initiated, Miles Inc. was the basic producer of ODM. On September 1993, Miles requested voluntary cancellation of all ODM products, and on June 1994, Miles submitted an application to transfer all products to Gowan Company. Gowan Company signed a Settlement Agreement with the Agency in September 1994. At the time that Miles requested voluntary cancellation of its products, the due dates for data to support reregistration of ODM were approaching and subsequently lapsed. Therefore, the Agency required risk mitigation concessions from Gowan to allow ODM products to remain on the market while the required data were being

generated. Gowan agreed not to market ODM on **citrus, field corn, popcorn, onions, pears, safflower, snap beans, sorghum, and turnips**. However, the tolerances were to be retained to allow these uses to be potentially reinstated after EPA's favorable review of the required data and completion of the dietary and worker risk assessments.

Tolerances are established for the combined residues of oxydemeton-methyl and its cholinesterase-inhibiting metabolites in/on various raw agricultural plant and animal commodities [40 CFR §180.330(a) and (b)] and processed feed commodities [40 CFR §186.3050]. The chemical structures and full chemical names of ODM residues of concern are presented in Figure 1. Adequate methods are available for the enforcement of tolerances for plant commodities.

Figure 1. Chemical Names and Structures of ODM Residues of Concern in Plant and Animal Commodities.

Common Name Chemical Name	Chemical Structure	Common Name Chemical Name	Chemical Structure
Oxydemeton-methyl; ODM		Oxydemeton-methyl sulfone; ODMS	
S-[2-(ethylsulfenyl)-ethyl] O,O-dimethyl phosphorothioate		S-[2-(ethylsulfonyl)-ethyl] O,O-dimethyl phosphorothioate	

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

A REFS search, conducted on 05/27/97, identified one ODM end-use product (EPs) registered under FIFRA Section 3 to Gowan Company, with registered uses on food/feed crops. This EP, including the associated Special Local Need (SLN) registrations under FIFRA Section 24 (c), are listed in Table A1.

Table A1. ODM EPs with Food/Feed Uses Registered to Gowan Company.

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
10163-220 ¹	01/07/97	2 lb/gal EC	Metasystox®-R Spray Concentrate

¹ Including SLN Nos. CA950002, FL960006, ID950001, ID950002, NV940005, OR940053, OR940054, WA950002, WA950003, and WA950004.

For the purpose of generating this Residue Chemistry Science Chapter, HED examined the currently registered food/feed use patterns on EPA Reg. No. 10163-220 (accepted 1/7/97) and reevaluated the available residue chemistry database for adequacy in supporting these use patterns. The use site/patterns deleted from Gowan's marketing labels in accordance with Gowan's settlement agreement with the Agency dated 9/30/94 (field corn, popcorn, sorghum, safflower, onions, pears, turnips and snap beans) have been based on Gowan's master label for EPA Reg. No. 10173-220 (accepted 9/18/95). A comprehensive summary of ODM food/feed use patterns, based on the product labels registered to Gowan Company, is presented in Table A2.

Nonfood Uses of ODM: HED has determined that the registered uses of ODM on the following sites, typically considered food use sites, should be classified as nonfood uses based on examination of the registered use patterns: nonbearing orchard crops including apples, apricots, cherries, crabapples, grapes, nectarines, peaches, plums, prunes, and quinces. As a result of the nonfood use classification, no residue chemistry data are required for reregistration of these uses provided that product labels continue to specifically prohibit harvest within one year of application.

A tabular summary of the residue chemistry science assessments for reregistration of ODM is presented in Table B. The status of reregistration requirements for each guideline topic listed in Table B is based on the use patterns registered by the basic producer, Gowan Company. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

The following label amendments are required to incorporate the parameters of use patterns reflected in the submitted field trials. The required label amendments are also presented in the endnote for GLN 860.1200 (Directions for Use) and in the endnotes for specific crops under GLN 860.1500 in Table B.

General: Label amendments are required for all ODM end-use products to specify that application using aerial equipment, when allowed, should be made in a minimum of 2 gal/A, or 10 gal/A for orchard crops.

Cabbage: The registrant must either modify product labels to increase the PHI to 10 days or propose an increased tolerance for residues in/on cabbage.

Eggplant: Data on peppers can be translated to eggplant provided that the product label for the 2 lb/gal EC formulation [EPA Reg. No. 10163-220] is revised to make the use pattern for eggplant identical to that of peppers.

Oranges: Provided that product labels are amended to specify that aerial applications be made in a minimum of 10 gal/A and to specify a maximum amount of active ingredient allowed per acre, no additional field trial data for oranges will be required. This maximum rate must be supported by adequate residue data.

Walnuts: The registrant must revise the product label for walnuts to specify a maximum amount of active ingredient allowed per acre. This maximum rate must be supported by adequate residue data.

Alfalfa: Based on the available field trial data for alfalfa forage and hay, label revisions are required to specify a maximum of 2 applications per season.

Clover: Based on the available field trial data for clover forage and hay, label revisions are required to specify a maximum of 3 applications per season and a PHI of 14 days.

Cotton: In lieu of conducting additional field trials depicting ODM residues of concern in/on cotton harvested 14 days following the last of three foliar applications at 0.5 lb ai/A, the registrant intends to amend the 2 lb/gal EC (EPA Reg. No. 10163-220) product label to allow only two applications per season at 0.5 lb ai/A. In addition, the registrant must remove the restriction against the grazing or feeding gin trash to dairy or meat animals from the product label; the Agency considers such restrictions to be impractical.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in cabbage, sugar beets, and sweet corn have been submitted and evaluated.

The HED Metabolism Committee (3/6/97) determined that ODM and oxydemeton-methyl sulfone (ODMS) are the residues to be regulated in plant commodities (see Figure 1). The Committee also determined that for dietary risk assessment, the residues to be considered are ODM, ODMS, desmethyl ODM, and desmethyl ODMS for plant commodities. In response to the 3/6/97 Metabolism Committee recommendation that the registrant conduct studies on the cholinesterase-inhibition activity of the desmethyl metabolites, Gowan submitted preliminary *in vitro* cholinesterase data (TIWET Study Report #09745; D239546 by D. Anderson dated 10/2/97).

The HED Metabolism SARC (9/4/97) has made a preliminary assessment of the *in vitro* cholinesterase data. The Committee agreed the preliminary data did not indicate cholinesterase inhibition for the oxydemeton-methyl desmethyl metabolites in rat whole brain preparations. This assessment, however, is contingent on submission of an acceptable full report on the conditions, supporting data on optimization of the incubation times and time course of the determinations, submission of all the experimental data associated with the submission and the acceptability of that report. Tentatively, the desmethyl metabolites will be dropped from the dietary risk assessment and the tolerance expression for plants will continue to include ODM and ODMS.

GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled. Acceptable studies depicting the qualitative nature of the residue in ruminants and poultry have been submitted and evaluated. Findings from older ruminant and poultry metabolism studies, which contrasted with the acceptable studies, were also considered. ODM is metabolized in ruminants and poultry by sequential loss of phosphate, methylation, and oxidation. The major metabolites in poultry and ruminants are sulfonyl sulfinylethanes, sulfinyl sulfinylethanes, and sulfonyl sulfonylethanes. Parent ODM was detected only in milk. The HED Metabolism Committee (3/6/97) has determined that ODM is the residue to be regulated in animal commodities.

GLN 860.1340: Residue Analytical Methods

Adequate methods are available for data collection and tolerance enforcement for plant and animal commodities. The Pesticide Analytical Manual (PAM) Vol. II lists a GLC method (Method I), using phosphorus-sensitive thermionic detection, for the determination of residues of ODM and its metabolite in/on plant commodities; this method involves oxidation of ODM to ODMS and determination of residues as ODMS. An equivalent method for animal commodities is Method No. 27004 which has undergone successful Agency validation trial. Methods used for data collection for plant commodities include GLC methods similar to the enforcement method and adequate colorimetric methods. Adequate method validation data have been submitted for the colorimetric and GLC data collection methods for the detection of ODM and ODMS only.

Radiovalidation (MRID 44369191) of the modified PAM Vol. II method using [¹⁴C]sample matrices from the sweet corn, sugarbeet, cabbage and ruminant (milk) metabolism studies have been submitted are currently in review (D239291).

In conjunction with requested proposals for revised tolerances for corn forage, field corn grain, and walnuts (see "Tolerance Reassessment Summary" section), the registrant must submit additional method validation data for these commodities at the proposed tolerance levels.

GLN 860.1360: Multiresidue Methods

The current FDA multiresidue method determines ODM and ODMS. The 2/97 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that ODM and ODMS are completely recovered (>80%) using Multiresidue Method Section 302 (Luke Method; Protocol D).

GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data are partially fulfilled. As requested in the Oxydemeton-Methyl Reregistration Standard Update dated 1/17/92, the sample storage intervals and conditions for all residue data submitted in support of tolerances must be supplied. In addition, storage stability data are needed for processed commodities and livestock commodities.

The submitted storage stability data are acceptable. They indicate that residues of ODM and ODMs are stable under frozen storage conditions for up to 24 months in/on broccoli, lettuce, pears, sugar beets, sweet corn (K+CWHR), sweet corn grain, and forage, and walnuts and for up to 12 months in/on sweet corn fodder. The 24-month sweet corn fodder data will be submitted as a report amendment. The matrices chosen in the subject study sufficiently represent all types of raw agricultural commodities (RACs) for which oxydemeton-methyl is registered.

GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on the following RACs will be considered fulfilled pending label revisions and/or tolerance adjustments: beans (succulent), broccoli, broccoli raab, Brussels sprouts, cabbage, clover forage and hay, corn grain (field and pop), corn forage, cottonseed, cucumbers, eggplant, filberts, grapefruit, lemons, lettuce (head), melons (cantaloupes and watermelons), mint hay, onions (dry bulb), oranges, pears, peppers, pumpkins, safflower, grain sorghum forage and grain, squash (summer and winter), strawberries, sugar beets and sugar beet tops, turnips and turnips tops, and walnuts. Overall, adequate field trial data depicting ODM residues of concern following treatments according to the maximum registered use patterns have been submitted for the RACs listed above. Label revisions are required for some crops in order to reflect current Agency policies and/or to reflect the parameters of use patterns for which field trial data are available. Refer to the "Tolerance Reassessment Summary" for recommendations regarding appropriate tolerance levels.

The available data for broccoli will be translated to support use of ODM on broccoli raab and cauliflower. The available data for peppers will be translated to support use of ODM on eggplant.

Additional field trial data are required for the following RACs: alfalfa forage, hay, and seed; cotton gin byproducts; sweet corn (K+CWHR); sweet corn stover; and grain sorghum stover.

Provided that the label for the 2 lb/gal EC (EPA Reg. No. 10163-220) formulation prohibits harvest within one year of application when the product is applied on non-bearing apples, apricots, grapes, and plums, no additional field trial data will be required; this use pattern has been determined to be a nonfood use. No additional field trial data are required for blackberries, bluegrass, peas, potatoes, and raspberries because there are currently no registered uses of ODM on these crops.

GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of citrus, field corn, cottonseed, mint, safflower, sorghum, and sugar beets have been fulfilled.

The ODM Update had required an additional processing study for sugar beets because the available data were insufficient to determine concentration factors; residues in sugar beets were nondetectable following treatment at a total of 11 lb ai/A, 2.5x the maximum registered rate at the time of the ODM Update. The application rate of 11 lb ai/A is 7.4x the current maximum seasonal rate for sugar beets and under current Agency policy, a processing study is not required if residues are nondetectable following treatment at $\geq 5x$. Therefore, the previously required processing study for sugar beets is no longer required.

The ODM Update had also required an additional processing study for field corn because the available study did not allow determination of concentration factors; the available data indicated detectable residues of ODM and ODMS in corn meal at 0.02 ppm and in flour at 0.03 ppm processed from field corn bearing nondetectable residues following treatment at 5x. Under current Agency policy, the available field corn processing data are sufficient to determine that tolerances for field corn processed commodities are not required. When the exaggeration rate of 5x is taken into account, the expected residues of ODM and ODMS in field corn meal (0.004 ppm) and flour (0.006 ppm) are below the reassessed tolerance for field corn grain (0.05 ppm). Therefore, the previously required processing study for field corn is no longer required.

No processing data are required to support nonfood use of ODM on non-bearing apples, apricots, grapes, and plums. No processing data are also required for potatoes because there are currently no registered uses of ODM on potatoes.

GLN 860.1480: Meat, Milk, Poultry, Eggs

Milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep:

The reregistration requirements for magnitude of the residue in meat and milk are fulfilled; reassessment of all available ruminant metabolism and feeding studies indicates that dosage information and raw data requirements noted in the 1992 Registration Standard Update are no longer needed.

The maximum theoretical dietary burdens of ODM to beef and dairy cattle are 10.3 ppm and 10.4 ppm, respectively (see table below); dietary burden calculations are tentative because data remain outstanding for alfalfa forage, a major livestock feed item. It should be noted that potential livestock feed items from crops deleted from Gowan's marketing label (**corn, safflower, turnips**) were not considered in the calculation of this dietary burden. However, inclusion of these feed items would not result in a dietary burden significantly greater than calculated below.

Calculation of maximum ruminant dietary burden for ODM.

Feed Commodity	Reassessed Tolerance (ppm)	% Dry Matter	Beef Cattle		Dairy Cattle	
			% of Diet	Burden (ppm)	% of Diet	Burden (ppm)
Alfalfa, forage	5.0	35	70	10.00	--	--
Clover, forage	5.0	30	--	--	60	10.00
Sorghum, grain	0.75	86	20	0.17	20	0.17
Dried citrus pulp	1.0	91	10	0.11	20	0.22
TOTAL			100	10.3	100	10.4

A dairy cattle feeding study was reviewed (CBRS Nos. 5172 and 5173, J. Garbus, 1/4/90) and it was determined that the study was inadequate because the registrant failed to provide complete raw data regarding the in-life portion of the study. This study conducted in 1987, along with data from an earlier ruminant feeding study conducted in 1972, provides sufficient information to reassess the adequacy of the existing tolerances for milk, meat, fat, and meat byproducts. No additional data are required.

Eggs and the fat, meat, and meat byproducts of poultry: Data from a previously submitted poultry feeding study were reviewed (CBRS Nos. 5172 and 5173, J. Garbus, 1/4/90) and deemed inadequate because the registrant failed to provide all the necessary raw data. Samples were not analyzed and raw data were not provided for some of the egg and poultry tissue samples. In addition, the dose levels in the study were imprecise and inaccurate and actual feeding levels were unknown because unused feed was not quantified. Residues of ODM and ODMS were <0.01 ppm in eggs from all sample intervals and reported dose levels (0.65, 1.95, and 6.5 ppm); residues were <0.01 ppm in tissues from hens dosed at 6.5 ppm in the feed.

A new poultry feeding study is not required to support reregistration of oxydemeton-methyl because no residues of toxicological concern were found in poultry commodities in a metabolism study conducted at a 6x feeding level. However, because these findings contrast with results of an earlier poultry metabolism study where oxydemeton-methyl was present in eggs and tissues, HED cannot conclude that there is no reasonable expectation of finite residues in poultry meat and eggs. Therefore, tolerances for residues of oxydemeton-methyl at the quantification limit of the method (0.01 ppm) in eggs and poultry fat, meat, and meat byproducts must be established.

The maximum theoretical dietary burden of ODM to poultry is tentatively calculated to be 1.70 ppm based on a diet consisting of 80% sorghum grain, and 10% each alfalfa meal and safflower meal; the dietary burden calculation is tentative because data remain outstanding for alfalfa.

Calculation of maximum poultry dietary burden for ODM.

Feed Commodity	Reassessed Tolerance (ppm)	Poultry	
		% of Diet	Burden (ppm)
Alfalfa, meal	11.0 ^a	10	1.10
Safflower, meal	1.0 ^b	10	0.10
Sorghum, grain	0.75	80	0.60
TOTAL		100	1.70

^a Using the currently established tolerance on alfalfa, hay, for seed. Additional field trial data are required to reassess this tolerance.

^b Using the reassessed tolerance on safflower, seed.

GLN 860.1400: Water, Fish, and Irrigated Crops

Oxydemeton-methyl is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1460: Food Handling

Oxydemeton-methyl is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLNs 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The reregistration requirements for confined/field rotational crop data are fulfilled (MRID 44128101, DP Barcode D231136). Radioactive residues accumulated at levels above 0.01 ppm in/on rotational commodities of lettuce, radishes, and wheat planted in sandy loam soil 30, 120, 210 and 365 days following application at 1X. Radioactive residues were adequately characterized and identified in/on rotational crops. Neither the parent nor ODMS were detected

in any rotational crop at any rotational intervals. Limited field rotational crops studies need not be conducted and rotational crop restrictions or tolerances need not be established.

Table A2. Food/Feed Use Patterns Subject to Reregistration for Oxydemeton-methyl (Case 0258).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Alfalfa (grown for seed)						
Foliar application Ground or aerial	2 lb/gal EC [10163-220] [ID950002] [NV940005]	0.5 lb/A	2	Not specified (NS)	21	Applications may be made in a minimum of 1 gal/A. Chaff from seed crop may be used for feed or forage, but the cut green crop may not be used for these purposes.
Beans, lima						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	21	Applications may be made in a minimum of 4 gal/A. A 21-day pregrazing interval (PGI) has been established.
Beets, sugar						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.75 lb/A	2	NS	30	Applications may be made in a minimum of 1 gal/A. A 30-day PGI has been established.
Broccoli						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	7	Applications may be made in a minimum of 1 gal/A.
Broccoli Raab						
Foliar application Ground or aerial	2 lb/gal EC [CA950002]	0.5 lb/A	3	NS	7	Use limited to CA. Applications may be made in a minimum of 5 gal/A by air.
Brussels sprouts						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	10	Applications may be made in a minimum of 1 gal/A.

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Cabbage (including tight-heading varieties of Chinese cabbage)						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.75 lb/A	3	NS	7	Applications may be made in a minimum of 1 gal/A.
Cauliflower						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	7	Applications may be made in a minimum of 1 gal/A.
Clover (grown for seed)						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	2	NS	21	See "Alfalfa (grown for seed)."
Corn, sweet						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	7 (single application) 21 (two/three applications)	Applications may be made in a minimum of 1 gal/A. A 7-day PGI (single application) or 21-day PGI (two/three applications) has been established.
Cotton						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.75 lb/A	3	NS	14	Use prohibited in CA. Applications may be made in a minimum of 1 gal/A. Grazing or feeding gin trash to dairy or meat animals is prohibited.
		0.5 lb/A	3	NS	14	Use limited to CA. Applications may be made in a minimum of 1 gal/A. Grazing or feeding gin trash to dairy or meat animals is prohibited.

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Cucumbers						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	2	NS	3	Applications may be made in a minimum of 1 gal/A.
Eggplant						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	7	Applications may be made in a minimum of 1 gal/A.
Filberts						
Bark band treatment Paint brush or low pressure sprayer	2 lb/gal EC [10163-220]	0.005 lb/inch of trunk diameter	1	NS	105	Use limited to OR and WA. Application may be made undiluted or diluted with an equal volume of water. Use on heavily stressed trees or on young trees with trunk diameters less than two inches is prohibited.
Cover spray application	2 lb/gal EC [WA950003]	0.5 lb/A	1	NS	116	Grazing or feeding cover crops to livestock is prohibited. The label for SLN No. WA950003 states that Metasystox-R may not be used in accordance with this labeling after 01/25/96.
Grapefruit						

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Cover spray application Ground or aerial	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	NS	7	Applications may be made in 100 gallons of water. Low-pressure, low-volume applications are permitted using aerial equipment with increased concentrations of the pesticide in a minimum of 10 gal of water/A.
Lemon						
Cover spray application Ground or aerial	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	NS	7	See "Grapefruit."
Lettuce, head						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	21 (also see "Use Limitations")	Applications may be made in a minimum of 1 gal/A. A 21-day PHI is in effect, except in AZ (all crops) and CA (fall and winter crops) where a PHI of 28 days has been established. In CA (spring and summer crops), PHIs of 14, 21, and 28 days have been established following 1, 2, or 3 applications, respectively.
Melons [including muskmelons (cantaloupes) and other melons]						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	3	NS	14	Applications may be made in a minimum of 1 gal/A.
Oranges						
Cover spray application Ground or aerial	2 lb/gal EC [FL960006]	0.375 lb/100 gal	2	NS	7	See "Grapefruit."

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Peppermint						
Foliar application Ground	2 lb/gal EC [10163-220]	0.75 lb/A	2	NS	14	Two applications may be made in a minimum of 20 gal/A with a 10- to 14-day retreatment interval.
Foliar application Ground or aerial	2 lb/gal EC [ID950001] [OR940054] [WA950002]	0.75 lb/A	2	NS	14	Use limited to ID, OR, and WA. Two applications may be made in a minimum of 1 gal/A with a 10- to 14-day retreatment interval. The label for SLN No. WA950002 states that Metasystox-R may not be used in accordance with this labeling after 01/25/96.
Peppers						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	2	NS	3	Applications may be made in a minimum of 1 gal/A.
Pumpkins						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	1	NS	14	Application may be made in a minimum of 1 gal/A.
Spearmint						
Foliar application Ground	2 lb/gal EC [10163-220]	0.75 lb/A	2	NS	14	See "Peppermint."
Foliar application Ground or aerial	2 lb/gal EC [ID950001] [OR940054] [WA950002]	0.75 lb/A	2	NS	14	See "Peppermint."

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Squash, summer						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	1	NS	3	Application may be made in a minimum of 1 gal/A.
Squash, winter						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	1	NS	14	Application may be made in a minimum of 1 gal/A.
Strawberries						
Delayed dormant (prebloom and post- final harvest) Ground or aerial	2 lb/gal EC [OR940053] [WA950004]	0.5 lb/A	3	NS	NS	Use limited to OR and WA. Applications may be made in a minimum of 1 gal/A. Application to fruit is prohibited. Three applications may be made each year, one application prebloom and two post-final harvest. The label for SLN No. WA950004 states that Metasystox-R may not be used in accordance with this labeling after 01/25/96.
Walnuts						
Cover spray application Ground or aerial	2 lb/gal EC [10163-220]	0.375 lb/100 gal [400 gal of finished spray per acre]	1	NS	30	Applications may be made in 100 gallons of water; but do not exceed 400 gallons of finished spray per acre per application. Low-pressure, low-volume applications are permitted using aerial equipment with increased concentrations of the pesticide in a minimum of 1 gal/A.

Table A2 (continued).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Limitations ¹
Watermelons						
Foliar application Ground or aerial	2 lb/gal EC [10163-220]	0.5 lb/A	2	NS	7	Application may be made in a minimum of 1 gal/A.

¹ The restricted entry interval (REI) for the 2 lb/gal EC (EPA Reg. No. 10163-220) formulation is 48 hours; the REI is increased to 72 hours in outdoor areas where average rainfall is less than 25 inches a year. The REI for the 2 lb/gal EC (SLN No. CA950002) formulation is 48 hours unless protective clothing specified on the product (Federal) label is worn.

Table B. Residue Chemistry Science Assessments for Reregistration of Oxydemeton-Methyl.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	N/A = Not Applicable	Yes ²	See Tables A1 and A2.
860.1300: Plant Metabolism	N/A	No	00116221, 00120079, 40404901 ³ , 40404902 ³ , 40404903 ³ , 40404904 ³ , 44048201 ⁴ , 44048202 ⁴ , 44065201 ⁵
860.1300: Animal Metabolism	N/A	No	00120208, 40404905 ³ , 40404906 ³ , 44000501 ⁶ , 44016101 ⁶
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes ⁷	00028722, 00029432, 00037507, 00037509, 00038467, 00038468, 00074357, 00096458, 00107030, 00120078, 00120208, 00120209, 00124231, 00152371, 00156398, 40670001 , 41085801 , 41085806 , 41085809 , 41085811 , 41085813 , 41085815 , 41085819 , 41146701 , 41146705 , 41146707 , 41247601 , 41288901 , 41288902 , 41319001 , 41514501
- Animal commodities	N/A	No	00038082, 40404907 ³

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
860.1360: Multiresidue Methods	N/A	No	41085822 ⁸
860.1380: Storage Stability Data	N/A	Yes ⁹	00037508, 00067459, 00095522, 00152371, 41085821 , 44228501 ¹⁰
860.1500: Crop Field Trials			
<u>Root and Tuber Vegetables Group</u>			
- Beets, sugar	0.3 [180.330(a)]	No	00095522, 00095523, 00120079
- Potatoes	0.1 [180.330(a)]	No ¹¹	00068261, 00095522, 00117130, 00152371
<u>- Turnips</u>	<u>0.3</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00107030</u>
<u>Leaves of Root and Tuber Vegetables Group</u>			
- Beets, sugar, tops	0.5 [180.330(a)]	No	00095522, 00095523, 00120079
<u>- Turnips, tops</u>	<u>2.0</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00107030</u>
<u>Bulb Vegetables (<i>Allium spp.</i>) Group</u>			
<u>- Onion, bulb</u>	<u>0.05</u> <u>[180.330(a)]</u>	<u>No</u>	<u>PP#3F1391</u>
<u>Leafy Vegetables (except <i>Brassica</i> Vegetables) Group</u>			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Lettuce (head)	2 [180.330(a)]	No	00038077, 00067474, 00074356, 00120079
<u>Brassica (Cole) Leafy Vegetables Group</u>			
- Broccoli	1 [180.330(a)]	No	00095522, 00120207, 00152371
- Broccoli raab	None established	No ¹²	
- Brussels sprouts	1 [180.330(a)]	No	00070840, 00120207, 00124231
- Cabbage	1 [180.330(a)]	No ¹³	00095522, 41085802 , 44032501 ¹⁴
- Cauliflower	1 [180.330(a)]	No ¹²	00120207
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Beans, succulent	0.5, beans, lima; <u>0.5, beans, snap</u> <u>[180.330(a)]</u>	No	00033834, 00038462, 00038463, 00038464, 00152371, 41146701 , 41146702
- Peas, succulent or dried	0.3, peas [180.330(a)]	No ¹¹	00036270, 00038464, 00152371, 41146703
<u>Foliage of Legume Vegetables Group</u>			

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Beans, vines and hay	2, beans, lima, forage; <u>2, beans, snap, forage</u> <u>[180.330(a)]</u>	No	00033834, 00038462, 00038463, 00038464, 00152371, 41146701, 41146702
- Peas, vines and hay	2, peas, forage; 8, peas, hay [180.330(a)]	No ¹¹	00036270, 00038464, 00152371, 41146703
<u>Fruiting Vegetables (except Cucurbits) Group</u>			
- Eggplant	1 [180.330(a)]	No ¹⁵	00075906, 00107031
- Peppers	0.75 [180.330(a)]	No	00075906, 00107031, 41085806, 41514502
<u>Cucurbit Vegetables Group</u>			
- Cucumbers	1 [180.330(a)]	No	00107030
- Melons	0.3 [180.330(a)]	No	00095522, 41085808, 41085810
- Pumpkins	0.3 [180.330(a)]	No ¹⁶	00095522, 00152371
- Squash, summer	1 [180.330(a)]	No ¹⁶	00095522

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Squash, winter	0.3 [180.330(a)]	No ¹⁷	00095522
<u>Citrus Fruits (<i>Citrus spp.</i> and <i>Fortunella spp.</i>) Group</u>			
- Grapefruit	1 [180.330(a)]	No	00075906, 00107031
- Lemon	1 [180.330(a)]	No	00075906, 00107031
- Orange	1 [180.330(a)]	No ¹⁸	00075906, 00107031, 41247601
<u>Pome Fruits Group</u>			
- Apples	1 [180.330(a)]	No ¹⁹	00037505, 00075906, 00107031
<u>- Pears</u>	<u>0.3</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00107030</u>
<u>Stone Fruits Group</u>			
- Apricots	0.5 [180.330(b)]	No ¹⁹	00103284, 00152371
- Plum (fresh prunes)	1 [180.330(a)]	No ¹⁹	00107031, 00120076
<u>Berries Group</u>			
- Blackberries	2 [180.330(a)]	No ¹¹	00095522
- Raspberries	2 [180.330(a)]	No ¹¹	00095522

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>Tree Nuts Group</u>			
- Filberts	0.05 [180.330(a)]	No	00067459, PP#3F1391
- Pecans	None established	No	
- Walnuts	0.3 [180.330(a)]	No ²⁰	00075902, 00075903, 00115769, 00152371, 41085813
<u>Cereal Grains Group</u>			
- <u>Corn, field, grain and aspirated grain fractions</u>	<u>0.5, grain</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00044956, 00090456, 00107030, 00152371, 41146704</u>
- <u>Corn, pop</u>	<u>0.5, grain</u> <u>[180.330(a)]</u>	<u>No</u>	
- Corn, sweet (K+CWHR)	0.5 [180.330(a)]	Yes ²¹	00044956, 00090456, 00107030, 00152371, 41085815 , 44041101 ¹⁴
- <u>Sorghum grain and aspirated grain fractions</u>	<u>0.75, grain</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00038079, 00135473, 00152371</u>
<u>Forage, Fodder, and Straw of Cereal Grains Group</u>			
- <u>Corn, field, forage and stover</u>	<u>3, forage;</u> <u>3, fodder</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00044956, 00090456, 00107030, 00152371, 41146704</u>
- <u>Corn, pop, stover</u>	<u>3, forage;</u> <u>3, fodder</u> <u>[180.330(a)]</u>	<u>No</u>	

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Corn, sweet, forage and stover	3, forage; 3, fodder [180.330(a)]	No	00044956, 00090456, 00107030, 00152371, 41085815
<u>- Sorghum (forage and stover)</u>	<u>2, forage</u> <u>[180.330(a)]</u>	<u>Yes ²²</u>	<u>00038079, 00135473,</u> <u>00152371</u>
<u>Grass Forage, Fodder, and Hay Group</u>			
- Bluegrass	None established	No ¹¹	
<u>Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group</u>			
- Alfalfa	11, chaff for seed; 5, green; 11, hay, for seed [180.330(a)]	Yes ²³	00090456, 00120209, 00152371, 41146706 , 44032502 ¹⁴
- Clover	11, chaff for seed; 5, green; 11, hay, for seed [180.330(a)]	No ²⁴	00052038, 00120209, 00152371, 41146707
<u>Miscellaneous Commodities</u>			
- Cotton, seed and gin byproducts	0.1 (seed) [180.330(a)]	Yes ²⁵	00117130, 41085820
- Grapes	0.1 [180.330(a)]	No ¹⁹	00038076

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
- Mint (peppermint and spearmint)	12.5, hay [180.330(a)]	No	00037506, 00037508, 00037510
<u>- Safflower</u>	<u>1</u> <u>[180.330(a)]</u>	<u>No</u>	<u>00038078, 00038082</u>
- Strawberries	2 [180.330(a)]	No	00120078 ²⁶ , 00141183 ²⁶ , 00152371, 41085811, 41085812 ²⁶
860.1520: Processed Food/Feed			
- Apples	None established	No ¹⁹	00037505
- Citrus	None established	No	00107031
- Corn, field	None established	No ²⁷	41288901
- Cottonseed	None established	No	41288902
- Grapes	None established	No ¹⁹	00038076, 00038087
- Mint	None established	No	00037506, 00037508, 00037510
- Plums	None established	No ¹¹	
- Potatoes	None established	No ¹⁹	
- Safflower	None established	No	00038078, 00038082

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References ¹
<u>- Sorghum</u>	<u>2.0, milled fractions (except flour)</u> <u>[186.3050]</u>	<u>No</u>	
- Sugar beet	None established	No ²⁸	41319001
860.1480: Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.01, fat, meat, and mby, and milk [180.330(a)]	No ²⁹	00036270, 00036271, 00036272, 00036273, 00038082, 40404908 ³
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No ³⁰	00118527, 00140798, 40404909 ³
860.1400: Water, Fish, and Irrigated Crops	None established	N/A	
860.1460: Food Handling	None established	N/A	
860.1850: Confined Rotational Crops	N/A	No ³¹	44128101
860.1900: Field Rotational Crops	None	No ³²	

- Bolded** references were reviewed in the Residue Chemistry Science Chapter of the Oxydemeton-Methyl Reregistration Standard Update dated 6/17/92. Unbolded references were reviewed in the Residue Chemistry Science Chapter of the Oxydemeton-Methyl Reregistration Standard dated 11/7/86. All other references were reviewed as noted.
- Label amendments are required for all ODM end-use products to specify that application using aerial equipment, when allowed, should be made in a minimum of 2 gal/A, or 10 gal/A for orchard crops.

Additional label amendments are required for specific crops; these required amendments are detailed in the endnotes for the crops under 860.1500.

Table B (*continued*)

3. CBRS Nos. 5172 and 5173, J. Garbus, 1/4/90.
4. CBRS No. 17414, DP Barcode D228101, 2/6/97, S. Funk.
5. CBRS No. 17632, DP Barcode D231138, 2/6/97, S. Funk.
6. CBRS No. 17315, DP Barcode D226974, 10/17/96, S. Funk.
7. In conjunction with proposals for revised tolerances, the registrant must submit method validation data for corn forage, field corn grain, and walnuts at the revised tolerance levels.
8. Data pertaining to the determination of ODM in/on food and feeds using FDA multiresidue Protocols; these data have been forwarded to FDA for review and inclusion in PAM, Vol. I.
9. Storage stability data are needed for processed commodities and livestock commodities (DP Barcode D210746, 6/21/95, S. Hummel). In addition, the sample storage intervals and conditions for all residue data submitted in support of tolerances must be supplied.
10. DP Barcode D234194, 10/14/97, P. Deschamp.
11. No additional data are required for the commodities of blackberries, bluegrass, peas, potatoes, and raspberries because there are currently no registered uses of ODM on these sites.
12. Data on broccoli and cabbage can be translated to broccoli raab. The registrant must submit a tolerance petition for broccoli raab which includes all available residue data that are pertinent to the registered use.

Data on broccoli can be translated to cauliflower.
13. The registrant must either modify product labels to increase the PHI to 10 days or propose an increased tolerance for residues in/on cabbage.
14. CBRS No. 17394, DP Barcode D227912, S. Funk, 2/27/97.
15. Data on peppers can be translated to eggplant provided that the product label for the 2 lb/gal EC formulation [EPA Reg. No. 10163-220] is revised to make the use pattern for eggplant identical to that of peppers.
16. Adequate data reflecting maximum registered use patterns of the EC formulation are available. Translated data from melons to summer squash for the 25% WP formulation, previously required in the ODM Update, are no longer needed because this formulation is not registered to the basic producer.
17. Adequate data reflecting maximum registered use patterns of the EC formulation are available. Translated data from melons to summer squash for the 25% WP formulation, previously specified in the ODM Update, are no longer needed because this formulation is not registered to the basic producer.
18. Provided that product labels are amended to specify that aerial applications be made in a minimum of 10 gal/A and to specify a maximum amount of active ingredient allowed per acre, no additional field trial data for oranges will be required.
19. Provided that labels for EPA Reg. No. 10163-220 continue to prohibit harvest within one year of application when the product is applied on non-bearing apples, apricots, grapes, and plums, no additional field trial data will be required; this use pattern has been determined to be a nonfood use.

Table B (continued)

20. The registrant must revise the product label to specify a maximum amount of active ingredient allowed per acre. This maximum rate must be supported by adequate residue data.
21. Additional field trial data depicting residues of ODM and ODMS in/on sweet corn are required to provide both adequate geographic representation and a greater number of results by which to judge possible variability (Endnote 14).
22. No field trial data are available for sorghum stover. Geographically representative field trial data reflecting the maximum registered application rate must be submitted for sorghum stover before the reregistration requirements for magnitude of the residue in/on sorghum stover can be considered fulfilled.
23. Additional field trial data depicting residues of ODM and ODMS in/on alfalfa forage and hay are required to provide adequate geographic representation. In addition, because there is a registered use for ODM on alfalfa grown for seed, data are required for alfalfa seed (Endnote 14).

Based on the available field trial data for alfalfa forage and hay, label revisions are required to specify a maximum of 2 applications per season.

24. Based on the available field trial data for clover forage and hay, label revisions are required to specify a maximum of 3 applications per season and a PHI of 14 days.
25. No additional data are required for cottonseed. In lieu of conducting additional field trials depicting ODM residues of concern in/on cotton harvested 14 days following the last of three foliar applications at 0.5 lb ai/A, the registrant intends to amend the 2 lb/gal EC (EPA Reg. No. 10163-220) product label to allow only two applications per season at 0.5 lb ai/A. In addition, the registrant must remove the restriction against the grazing or feeding gin trash to dairy or meat animals from the product label; the Agency considers such restrictions to be impractical.

The Agency currently recognizes cotton gin byproducts (commonly called gin trash which include the plant residues from ginning cotton consisting of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt) as a RAC (Table 1, OPPTS 860.1000). Data depicting the magnitude of ODM residues of concern in/on cotton gin byproducts following application(s) of a representative formulation according to the maximum registered use patterns are required. Cotton must be harvested by commercial equipment (stripper and mechanical picker) to provide an adequate representation of plant residue for the ginning process. A minimum of three field trials for each type of harvesting (stripper and mechanical picker) are required, for a total of six field trials. An appropriate tolerance for this RAC should be proposed once acceptable data have been submitted and evaluated.

26. CBRS No. 17876, DP Barcode D235179, 6/12/97, S. Funk.
27. The previously required processing study for field corn is no longer required. Under current Agency policy, the available field corn processing data are sufficient to determine that tolerances for field corn processed commodities are not required.
28. The previously required processing study for sugar beets is no longer required. The ODM Update had required an additional processing study for sugar beets because the available data were insufficient to determine concentration factors; residues in sugar beets were nondetectable following treatment at a total of 11 lb ai/A, 2.5x the maximum registered rate at the time of the ODM Update. The application rate of 11 lb ai/A is 7.4x the current maximum seasonal rate for sugar beets and under current Agency policy, a processing study is not required if residues are nondetectable following treatment at $\geq 5x$.
29. No additional ruminant feeding study data are required.

Table B (*continued*)

30. A new poultry feeding study is not required to support reregistration of oxydemeton-methyl. However, tolerances for residues of oxydemeton-methyl at the quantification limit of the method (0.01 ppm) in eggs and poultry fat, meat, and meat byproducts must be established.
31. DP Barcode D231136, P. Deschamp, 9/16/97.
32. Neither the parent nor ODMS were detected in any rotational crop at any interval. Limited field rotational crop studies need not be conducted and rotational crop restrictions or tolerances need not be established.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of ODM in/on plant and animal commodities [40 CFR §180.330(a) and (b)] and processed feed [40 CFR §186.3050] are presently expressed in terms of the combined residues of ODM and its cholinesterase-inhibiting metabolites. Based on the available plant and animal metabolism studies, the HED Metabolism Committee (3/6/97) determined that ODM and oxydemeton-methyl sulfone (ODMS) are the residues to be regulated in plant commodities (see Figure 1). The Committee also determined that for dietary risk assessment, the residues to be considered are ODM, ODMS, desmethyl ODM, and desmethyl ODMS for plant commodities. In response to the 3/6/97 Metabolism Committee recommendation that the registrant conduct studies on the cholinesterase-inhibition activity of the desmethyl metabolites, Gowan submitted preliminary *in vitro* cholinesterase data (TIWET Study Report #09745).

The HED Metabolism SARC (9/4/97) has made a preliminary assessment of the *in vitro* cholinesterase data. The Committee agreed the preliminary data did not indicate cholinesterase inhibition for the oxydemeton-methyl sulfone metabolites in rat whole brain preparations. This assessment, however, is contingent on submission of an acceptable full report on the conditions, supporting data on optimization of the incubation times and time course of the determinations, submission of all the experimental data associated with the submission and the acceptability of that report. Tentatively, the desmethyl metabolites will be dropped from the dietary risk assessment and the tolerance expression for plants will continue to include ODM and ODMS.

The tolerances listed in 40 CFR need to be reorganized in order to: (i) incorporate the recommendations made by the HED Metabolism Committee concerning the ODM residues of concern that need to be regulated for plant and animal commodities; and (ii) conform with the requirements of the Food Quality Protection Act (FQPA). The FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities under a single section of the statute, Section 408. The FQPA authorizes the conversion of all existing Section 409 tolerances for pesticide residues in processed food/feed into Section 408 tolerances.

The listing of ODM tolerances under 40 CFR §180.330 should be subdivided into parts (a) and (b). Part (a) should be reserved for plant commodities with permanent tolerances, and if needed, for processed food/feed items [formerly listed under 40 CFR §186.3050]. Part (b) should be reserved for animal commodities. Tolerances with regional registration [formerly listed under 40 CFR §180.330(b)] are no longer required. The reorganization of ODM tolerances should be conducted as depicted below in Table C.

Table C. Reorganization of ODM Tolerances Required Under 40 CFR.

40 CFR Section	Section Reserved For	Tolerance Expression
§180.330 (a)	Raw Agricultural and Processed Food/Feed Commodities	ODM and ODMS.
§180.330 (b)	Animal Commodities	ODM <i>per se</i>

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, ODM tolerances for certain commodities which have been removed from Table 1 need to be revoked since there are no longer significant livestock feed items for these commodities, and some commodity definitions must be corrected. Also, tolerances for commodities for which there are currently no registered uses of ODM and for which uses are non-food uses based on the current use pattern need to be revoked. In addition, the tolerances for commodities from crops which have been removed from Gowan's marketing label may be revoked pending the Agency's decision to reinstate these uses. A summary of the ODM tolerances proposed for revocations is presented in Table D.

Table D. Proposed ODM Tolerance Revocations¹.

No Currently Registered Uses	Non-Food Non-bearing	No longer significant feed items (Table 1)	Uses Deleted From Gowan's Marketing Label per 9/30/94 Settlement Agreement
peas pea forage pea hay potatoes raspberries blackberries	apples apricots grapes plums (fresh prunes)	clover chaff lima bean forage	(citrus) field corn fodder field corn grain field corn forage onions, bulb pears popcorn forage popcorn popcorn fodder safflower snap bean forage ² snap beans sorghum grain grain sorghum forage sorghum milled fractions ² turnip tops turnips

¹ The tolerances for commodities from crops which have been removed from Gowan's marketing label may be revoked pending the Agency's decision to reinstate these uses.

² No longer significant feed items (Table 1)

Tolerances to be Listed Under 40 CFR §180.330(a):

Adequate data are available to reassess the established tolerances for the following commodities which appear on Gowan's current marketing label dated 1/7/97, **as defined:** beans, lima; beets, sugar; beets, sugar, tops; broccoli; Brussels sprouts; cabbage; cauliflower; clover, green; clover, hay, for seed; cottonseed; cucumbers; eggplant; filberts; lettuce, head; melons; mint, hay; peppers; pumpkins; squash (summer and winter); strawberries;

Adequate data are available to reassess the established tolerances for the following commodities which appear only on Gowan's Master Label dated 9/18/95, **as defined:** beans, snap; turnips, and turnips, tops; onions, dry bulb; sorghum, grain; safflower; corn, forage; corn, grain; pears;

Adequate data are available (pending required label amendments) to reassess the established tolerances for cabbage (alternatively, the tolerance must be increased), eggplant, oranges, grapefruit, lemons, walnuts, clover, and cottonseed.

Insufficient field trial data are available to reassess the tolerances for the following commodities, **as defined:** alfalfa, chaff, for seed; alfalfa, green; alfalfa, hay, for seed; corn, fodder; corn, fresh (inc. sweet K+CWHR); and grain sorghum forage (use reinstatement).

The available residue data indicate that the following revisions to the tolerance levels should be made: the established levels for beans, lima; beets, sugar; clover, hay, for seed; corn, forage; corn, grain; cottonseed; eggplant; melons; peppers; and pumpkins should be lowered; and the established tolerance level for cabbage should be increased. We note that the registrant has the option of altering the use pattern for cabbage instead of proposing an increased tolerance.

The established tolerances for blackberries; peas; peas, forage; pea, hay; potatoes; raspberries; and blackberries should be revoked as there are currently no registered uses of ODM on these commodities.

The established tolerances for apples, apricots, grapes, and plums (fresh prunes) should be revoked since the Agency has determined that use of ODM at these sites, typically considered food use sites, should be classified as nonfood use based on examination of the registered use patterns.

The established tolerances for lima bean forage, snap bean forage, and clover chaff should be revoked since these items are no longer considered significant livestock feed items (Table 1, OPPTS GLN 860.1000).

Tolerances To Be Proposed Under 40 CFR §180.330(a):

The registrant must propose a tolerance of 2 ppm for ODM residues of concern in/on Broccoli raab. The tolerance petition should include all available residue data that are pertinent to the registered use. The proposed tolerance is based on the translation of data from broccoli and cabbage treated according to the maximum use pattern.

A tolerance must be proposed for grain sorghum stover. In addition, as a result of changes in Table 1 (GLN 860.1000), a tolerance is now required for cotton gin byproducts and popcorn. The appropriate tolerance levels for these commodities will be determined when adequate field trial data have been submitted and evaluated.

Tolerances to be Listed Under 40 CFR §180.330(b):

The tolerance currently listed under §180.330(b) is established with regional registration. The tolerance for apricots should be revoked since the Agency has determined that use of ODM on non-bearing apricots is a nonfood use and does not require a tolerance.

Adequate data are available to reassess the tolerances for milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep.

Tolerances to be Proposed Under 40 CFR §180.330(b):

Tolerances for residues of oxydemeton-methyl at the quantification limit of the method (0.01 ppm) in eggs and poultry fat, meat, and meat byproducts must be established.

Pending Tolerance Petitions:

1984; PP#4E3033: IR-4 proposed a tolerance of 1 ppm for residues of ODM and its cholinesterase-inhibiting metabolites in/on bok choy.

1984; PP#4E3032: IR-4 proposed a tolerance of 1 ppm for residues of ODM and its cholinesterase-inhibiting metabolites in/on collards, kale, and kohlrabi.

1982; PP#7F1886/7H5155: Mobay proposed tolerances of 0.2, 5, and 0.6 ppm for residues of ODM and its cholinesterase-inhibiting metabolites in/on wheat grain, straw, and bran, respectively.

1980; PP#0F2379: Mobay proposed tolerances of 0.01 and 0.2 ppm for residues of ODM and its cholinesterase-inhibiting metabolites in/on dried beans and bean vine, respectively.

1980; PP#0F2327: Mobay proposed tolerances of 0.01 and 0.05 ppm for residues of ODM and its cholinesterase-inhibiting metabolites in/on pecans and in/on pecan shells, respectively.

Table E. Tolerance Reassessment Summary for Oxydemeton-methyl.

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.330(a)			
Alfalfa, chaff, for seed	11	TBD ¹	Additional data are required. [Alfalfa, seed]
Alfalfa, green	5	TBD	Additional data are required. [Alfalfa, forage]
Alfalfa, hay, for seed	11	TBD	Additional data are required. [Alfalfa, hay]
Apples	1	Revoke	Nonbearing uses have been determined to be nonfood use.
Beans, lima	0.5	0.2	The reassessed tolerance is based on the maximum combined residues of <u>≤0.15 ppm</u> in/on treated samples of lima beans according to maximum use pattern. [Bean, succulent]
Beans, snap	0.5		
Beans, lima, forage	2	Revoke	No longer considered a significant livestock feed item (Table 1, OPPTS 860.1000).
Beans, snap, forage	2		
Beets, sugar	0.3	0.3	[Beet, sugar]
Beets, sugar, tops	0.5	0.5	[Beet, sugar, tops]
Blackberries	2	Revoke	There are currently no registered uses on blackberries.
Broccoli	1	1	
Brussels sprouts	1	1	
Cabbage	1	2	The reassessed tolerance is based on the maximum combined residues of <u>1.22 ppm</u> in/on treated samples of cabbage according to maximum use pattern. The registrant may choose to increase the PHI in lieu of proposing an increased tolerance.
Cauliflower	1	1	
Clover, chaff, for seed	11	Revoke	No longer considered a significant livestock feed item (Table 1, OPPTS GLN 860.1000).
Clover, green	5	5	[Clover, forage]

Table E (continued).

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Clover, hay, for seed	11	10	The reassessed tolerance is based on the maximum combined residues of <u>9.84 ppm</u> in/on treated samples according to maximum use pattern. [Clover, hay]
Corn, fodder	3	TBD	Additional storage stability data are required. [Corn, stover]
Corn, forage	3	1	The reassessed tolerance is based on the maximum combined residues of <u>0.9 ppm</u> in/on treated samples according to maximum use pattern.
Corn, fresh (inc sweet K+CWHR)	0.5	TBD	Additional data are required. [Corn, sweet (K+CWHR)]
Corn, grain	0.5	0.05	[Corn, field, grain]
Corn, pop			[Corn, pop, grain]
Cottonseed	0.1	0.02	Provided labels are amended such that ODM use on cotton is limited to two applications per season, the reassessed tolerance is based on the maximum combined residues of <u>≤0.02 ppm</u> in/on treated samples. [Cotton, undelinted seed]
Cucumbers	1	1	
Eggplant	1	0.6	The reassessed tolerance is based on the translation of data on peppers and the maximum combined residues of <u>0.58 ppm</u> in/on treated samples according to maximum use pattern. Reassessment is also contingent upon the requested label amendment (revise product label for the 2 lb/gal EC to make the use pattern for eggplant identical to that of peppers).
Filberts	0.05	0.05	
Grapefruit	1	1	
Grapes	0.1	Revoke	Nonbearing uses have been determined to be nonfood use.
Lemons	1	1	
Lettuce, head	2	2	

Table E (continued).

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Melons	0.3	0.2	The reassessed tolerance is based on the maximum combined residues of <u>≤0.2 ppm</u> in/on treated samples according to maximum use pattern.
Mint, hay	12.5	12.5	[Mint, tops (leaves and stems)]
Onions, dry bulb	0.05	0.05	[Onion, bulb]
Oranges	1	1	
Pears	0.3	0.3	
Peas	0.3	Revoke	There are currently no registered uses on peas.
Peas, forage	2		
Peas, hay	8		
Peppers	0.75	0.6	The reassessed tolerance is based on the maximum combined residues of <u>0.58 ppm</u> in/on treated samples according to maximum use pattern.
Plums (fresh prunes)	1	Revoke	Nonbearing uses have been determined to be nonfood use.
Potatoes	0.1	Revoke	There are currently no registered uses on potatoes.
Pumpkins	0.3	0.2	The reassessed tolerance is based on the maximum combined residues of <u><0.1 ppm</u> in/on treated samples according to maximum use pattern.
Raspberries	2	Revoke	There are currently no registered uses on raspberries.
Safflower	1.0	1.0	[Safflower, seed]
Sorghum, forage	2.0	2.0	[Sorghum, grain, forage]
Sorghum, grain	0.75	0.75	
Squash, summer	1	1	
Squash, winter	0.3	0.3	
Strawberries	2	2	
Turnips	0.3	0.3	[Turnip, tops]
Turnips, tops	2	2	[Turnip, tops (leaves)]
Walnuts	0.3	0.05	
Tolerances Listed Under 40 CFR §180.330(b)			

Table E (continued).

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Apricots	0.5	Revoke	Nonbearing uses have been determined to be nonfood use.
Tolerances Listed Under 40 CFR §186.3050			
Milled fractions of sorghum (except flour)	2.0	Revoke	No longer considered significant livestock feed items (Table 1, OPPTS 860.1000).
Tolerances to be Proposed Under 40 CFR §180.330(a)			
Broccoli raab	None	2	The proposed tolerance is based on the translation of data from broccoli and cabbage.
Corn, pop	None	0.05	The proposed tolerance is based on data for corn grain.
Cotton, gin byproducts	None	TBD	Data for cotton gin byproducts are now required as a result of changes in Table 1 (GLN 860.1000).
Sorghum, stover	None	TBD	Field trial data must be submitted.
Tolerances to be Listed Under 40 CFR 40 CFR §180.330(b)			
Cattle, fat	0.01	0.01	
Cattle, mbyp	0.01	0.01	
Cattle, meat	0.01	0.01	
Goats, fat	0.01	0.01	
Goats, mbyp	0.01	0.01	
Goats, meat	0.01	0.01	
Hogs, fat	0.01	0.01	
Hogs, mbyp	0.01	0.01	
Hogs, meat	0.01	0.01	
Horses, fat	0.01	0.01	
Horses, mbyp	0.01	0.01	
Horses, meat	0.01	0.01	
Milk	0.01	0.01	
Sheep, fat	0.01	0.01	
Sheep, mbyp	0.01	0.01	
Sheep, meat	0.01	0.01	
Tolerances to be Proposed Under 40 CFR 40 CFR §180.330(b)			

Commodity	Current Tolerance, ppm	Tolerance Reassessment, ppm	Comment/ [Correct Commodity Definition]
Poultry fat, meat, and meat byproducts	None	0.01	Tolerances for residues of oxydemeton-methyl at the quantification limit of the method (0.01 ppm) in eggs and poultry fat, meat, and meat byproducts must be established.
Poultry eggs	None	0.01	

¹ TBD = to be determined.

DIETARY RISK ASSESSMENT SUMMARY

Adequate plant and animal metabolism data and animal and plant magnitude of the residue data are available for most commodities with tolerances. Adequate data are also available for processed plant commodities as well. The registrant is required to determine appropriate tolerance levels for alfalfa (chaff, green, and hay), corn fodder, corn fresh (K+CWHR), cotton gin byproducts, and sorghum stover. HED does not expect that these to-be-proposed/determined tolerances would significantly alter any dietary assessment. HED thus concludes that a reasonably reliable risk assessment can be performed for the currently-registered uses of oxydemeton-methyl: the established tolerances and/or the revised tolerance recommendations presented in Table E of this document are appropriate for exposure/risk assessment purposes.

For chronic (non-cancer) risk concerns, a DRES analysis (R. Griffin, 11/21/97) was performed using the RfD of 0.0005 mg/kg/day. Assuming tolerance level residues, percent crop treated estimates from BEAD (S. Wise 9/17/97), and anticipated residues for milk (B. Cropp-Kohlligian, 12/97), DRES calculated that 38% of the RfD for the U.S. population was occupied. The highest subgroup was non-nursing infants (<1 year old) at 65% of the RfD occupied.

For acute dietary concerns, a Tier 1 DRES analysis was conducted using the acute dietary endpoint of 0.05 mg/kg/day. Assuming tolerance level residues, the estimated margin of exposure (MOE = NOEL/Exposure) for the all population subgroups was <5. An MOE of 100 is considered to be adequately protective for acute dietary exposure to oxydemeton-methyl; thus, acute dietary risk is a significant issue for ODM reregistration. HED does not believe that a Tier 2 refinement (utilization of average residue data for food forms that are typically mixed) of acute dietary exposure would significantly alter the risk calculation. It is recommended that the registrant submit an acute dietary exposure analysis where probabilistic assessments using Monte Carlo techniques are utilized. It is also recommended that the registrant consult with HED on acceptable data sources and other considerations prior to initiation of this analysis.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for residues of ODM in/on various raw agricultural and animal commodities. The Codex MRLs are expressed in terms of the sum of oxydemeton-methyl, demeton-S-methyl, and demeton-S-methylsulphon expressed as oxydemeton-methyl. The Codex MRLs and the U.S. tolerances will be incompatible when the U.S. tolerance expression is revised to include both residues of ODM and ODMS for plant commodities and ODM *per se* for animal commodities. A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in Table F.

Table F. Codex MRLs and applicable U.S. tolerances for oxydemeton-methyl.
Recommendations are based on conclusions following reassessment of U.S. tolerances (see Table E).

Codex ¹			Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)	Step		
Alfalfa fodder	5	6	TBD ²	
Apple	1	6	None	The U.S. tolerance will be revoked.
Barley	0.2	6	None	
Beans (dry)	0.01 (*) ³	3	None	
Broccoli	1	6	1	
Brussels sprouts	1	6	1	
Cabbage, Savoy	0.01 (*)	6	2	
Cabbage, Head	1	6	2	
Cattle fat	0.05 (*)	6	0.01	
Cauliflower	0.01 (*)	6	1	
Cherries	1	6	None	
Clover hay or fodder	5	6	10	
Common bean (pods and/or immature seeds)	0.2	6	0.2 [bean, succulent]	
Cotton seed	0.05	6	0.02	
Cucumber	0.5	6	1	
Derived milk products	0.05	6	0.01	
Egg plant	0.2	6	0.6	
Eggs	0.05 (*) ²	6	0.01	

Table E (continued).

Codex ¹			Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)	Step		
Garden pea (young pods)	0.1	6	None	The U.S. tolerance will be revoked.
Grapefruit	0.1	6	1	
Grapes	0.5	6	None	The U.S. tolerance will be revoked.
Kale	0.05	6	None	
Kohlrabi	0.01 (*)	6	None	
Lemon	1	6	1	
Lettuce, leaf	2	6	None	
Lima bean (young pods and/or immature beans)	0.2	3	0.2 [bean, succulent]	
Maize	0.2	6	0.05	
Maize fodder	5	6	TBD	
Mandarin	0.5	6	1	
Meat of cattle, pigs & sheep	0.05 (*)	6	0.01	
Milks	0.01 (*)	6	0.01	
Mints	20	3	12.5 [mint, hay]	
Oats	0.2	6	None	
Onion, Bulb	0.05	6	None	The U.S. tolerance will be revoked.
Oranges, Sweet, Sour	0.5	6	1	
Peach	1	6	None	
Pear	0.5	6	0.3	
Peas (dry)	0.01 (*)	3	None	The U.S. tolerance will be revoked.
Peppers	1	6	0.6	
Pig fat	0.05 (*)	6	0.01	

Table E (continued).

Codex ¹			Reassessed U.S. Tolerance, ppm	Recommendation And Comments
Commodity, As Defined	MRL (mg/kg)	Step		
Potato	0.2	6	None	The U.S. tolerance will be revoked.
Poultry fats	0.05 (*)	6	0.01	
Poultry meat	0.05 (*)	6	0.01	
Pumpkins	0.1 (*)	6	0.2	
Safflower seed	1	3	1.0	
Sheep fat	0.05 (*)	6	0.01	
Sorghum	0.5	6	0.75	
Sorghum forage (green)	1	3	2.0	
Sorghum straw and fodder, Dry	3	6	TBD	
Squash, Summer	0.1 (*)	6	1	
Strawberry	0.5	6	2	
Sugar beet	0.05 (*)	6	0.2	
Sugar beet leaves or tops	0.5	6	0.5	
Sweet corn (corn-on- the-cob)	0.05	3	TBD	
Sweet corn (kernels)	0.05	3	None	
Tomato	0.5	6	None	
Tree nuts	0.05 (*)	6	0.05 [walnuts] 0.05 [filberts]	
Turnip leaves or tops	5	6	2	
Turnip, Garden	0.1 (*) ²	6	0.3	
Watermelon	0.2	6	0.2	
Wheat	0.2	6	None	
Winter squash	0.1	6	0.3	

Table E (*continued*).

- ¹ It was reported that only alfalfa fodder, apple, barley, beans, broccoli, Brussels sprouts, cabbage (head & Savoy), cauliflower, clover hay or fodder, eggplant, grapefruit, grapes, kale, kohlrabi, lemon, lettuce (leaf), mandarin, orange (sweet, sour), pear, peas, peppers, plums, potato, squash (summer and winter), strawberry, sugar beet, tree nuts, watermelon, and wheat would be supported. The Committee decided not to discuss the individual MRLs and to postpone the consideration of this compound until new data have been submitted and reviewed by the JMPR (27.149). The Committee further postponed discussion awaiting the 1997 JMPR where the compound together with the related compound, would be evaluated (28.72).
- ² TBD = To be determined; residue data remain outstanding.
- ³ (*) = At or about the limit of detection.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CBRS Nos.:	5172 and 5173
Subject:	Oxydemeton-methyl (Metasystox-R). Registrant's Response to Residue Chemistry Requirements of Reregistration Standard. Plant and Animal Metabolism and Animal Feeding Studies.
From:	J. Garbus
To:	R. Engler and L. Rossi
Dated:	01/04/90
MRID(s):	40404901 through 40404909
CBRS No.:	6573
Subject:	90-ID-09. Section 18 Request for the Use of Oxydemeton-Methyl (ODM) on Bluegrass Grown for Seed.
From:	M. Metzger
To:	B. Cool/J. Tompkins and Toxicology Branch I
Dated:	05/04/90
MRID(s):	None
CBRS No.:	8362
DP Barcode:	D167300
Subject:	Metasystox-R (Oxydemeton-methyl). Impact of Craven Analytical Data on Registrations.
From:	M. Flood
To:	R. Forrest
Dated:	09/30/91
MRID(s):	None

CBRS No.: None
DP Barcode: None
Subject: Reregistration of Oxydemeton-Methyl: Addendum to Reregistration Standard Update; Chemical No. 58702; Case No. 0258.
From: C. Olinger
To: B. Lowery
Dated: 06/22/92
MRID(s): None

CBRS No.: 14937
DP Barcode: D210746
Subject: Oxydemeton-Methyl (058702) Reregistration Case No. 0258. Protocol for Storage Stability Studies.
From: S. Hummel
To: B. O'Keefe/L. Schnaubelt
Dated: 06/21/95
MRID(s): None

CBRS No.: 17315
DP Barcode: D226974
Subject: Oxydemeton Methyl (List A, Chemical 058702, Case 0258). Nature of the Residue in Ruminants.
From: S. Funk
To: P. Deschamp
Dated: 10/17/96
MRID(s): 44000501 and 44016101

CBRS No.: 17632
DP Barcode: D231138
Subject: Oxydemeton Methyl (List A, Chemical 058702, Case 0258). Nature of the Residue in Sugar Beets.
From: S. Funk
To: W. Hazel
Dated: 02/06/97
MRID(s): 44065201

CBRS No.: 17414
DP Barcode: D228101
Subject: Oxydemeton Methyl (List A, Chemical 058702, Case 0258). Nature of the Residue in Cabbage. Nature of the Residue in Sweet Corn.
From: S. Funk
To: W. Hazel
Dated: 02/06/97
MRID(s): 44048201 and 44048202

CBRS No.: 17394
DP Barcode: D227912
Subject: Oxydemeton Methyl (ODM): S-2-ethylsulfinyethyl-O,O-dimethyl phosphorothioate (Metasystox R), List A, Case 0258, Chemical 058702. Magnitude of the Residue in/on Corn, Cabbage, and Alfalfa.

From: S. Funk
To: P. Deschamp
Dated: 02/27/97
MRID(s): 44041101, 44032501, and 44032502

CBRS No.: None
DP Barcode: None
Subject: Oxydemeton Methyl (ODM): S-2-ethylsulfinyethyl-O,O-dimethyl phosphorothioate (Metasystox R), List A, Case 0258, Chemical 058702. Metabolism in Plants and Animals. The Metabolism Committee Meeting Held on January 21, 1997.

From: S. Funk
To: HED Metabolism Committee
Dated: 03/06/97
MRID(s): None

CBRS No.: 17876
DP Barcode: D235179
Subject: Oxydemeton-Methyl (List A, Chemical 058702, Case 0258). Strawberry Field Trials (860.1500). Gowan Company.

From: S. Funk
To: M Fox/K. Monk and W. Hazel
Dated: 6/12/97
MRID(s): 00120078, 00141183, and 41085812

DP Barcode: D231136
Subject: Oxydemeton-methyl: Confined/Field Accumulation in Rotational Crops.
From: P. Deschamp
To: M. Begley
Date: 9/16/97
MRID(s): 44128101

CBRS No.: 17834
DP Barcode: D234194
SUBJECT: Oxydemeton-methyl: Storage Stability of ODM and ODMS in Broccoli, Lettuce, Pears, Sugar Beets, Sweet Corn, and Walnuts.

From: P. Deschamp
To: Mary Begley
Dated: 10/14/97
MRID(s): 44228501

MASTER RECORD IDENTIFICATION NUMBERS

References Used To Support Reregistration

00028722 Olson, T.J. (1971) Determination of Meta-Systox-R Residues in Cottonseed and Walnuts by Thermionic Emission Gas Chromatography: Report No. 21590. Method dated Oct 15, 1971. (Unpublished study received Apr 9, 1980 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:242186-C)

00029432 Olson, T.J. (1971) An Interference Study for the Meta-Systox-R Residue Method for Crops: Report No. 30957. Method dated Sep 20, 1971. (Unpublished study received Feb 26, 1980 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 099269-G)

00033834 Mobay Chemical Corporation (1979) Synopsis of Metasystox-R Residue Chemistry on Beans. (Unpublished study received Jun 23, 1980 under 3125-111; CDL:099494-A)

00036270 Chemagro Corporation (1972) Recovery of Meta-Systox-R from Milk: Report No. 35409. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-B)

00036271 Chemagro Corporation (1973) Recovery of Meta-Systox-R from Cattle Tissue: Report No. 35410. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-C)

00036272 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: AROMATIC HYDROCARBON-72A-874: Report No. 35556. Rev. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-D)

00036273 Baychem Corporation (1973) Chemagro Division of Baychem Corporation Residue Experiment: AROMATIC HYDROCARBON-72A-874: Report No. 35557. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093953-E)

00037505 Chemagro Corporation (1973) Addition to Synopsis of Analytical Residue, and Flavor Information for Metasystox-R on Various Crops. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093954-A)

00037506 Chemagro Corporation (1972) Synopsis of Analytical and Residue Information for Metasystox-R on Mint. Summary of studies 093952-H through 093952-J, 093954-C, 093954-D and 093954-H through 093954-K. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093954-B)

00037507 Thornton, J.S.; Olson, T.J. (1973) [Determination of Meta-Systox-R in Lettuce, Sugar Beets and Mint by Gas Chromatography]: Report No. 21000. Includes method dated Oct 15, 1971. (Unpublished study including data found in 093952-G and report no. 35862, received Mar 27, 1974 under 4F1485; prepared in cooperation with Analytical BioChemistry Laboratories, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-D)

00037508 Coahran, D.R.; Jordan, J.C.; Legault, R.R. (1970) Pesticide Residue Analysis: Report No. 27040. (Unpublished study received Mar 27, 1974 under 4F1485; prepared by Washington State Univ., Agricultural Experiment Station, Dept. of Agricultural Chemistry, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-H)

00037509 Thornton, J.S. (1970) A study of the Possible Interferences of Other Pesticides with the Analytical Method for Meta-Systox-R on Crops, I. Test for the Compounds Registered on Mint: Report No. 29063. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL: 093954-I)

00037510 Analytical BioChemistry Laboratories (1973) Chemagro Division of Baychem Corporation Residue Experiment: 862-1230-72D: Report No. 35957. (Unpublished study including report nos. 35958, 35959, 35960..., received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093954-J)

00038076 Mobay Chemical Corporation (1975) [Metasystox-R Residues in Grapes, Raisins and Wine]. (Unpublished study received Jun 18, 1975 under 5F1643; CDL:094449-B)

00038077 Missouri Analytical Laboratories (1975) Metasystox-R Residues in Lettuce. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL: 094449-C)

00038078 Missouri Analytical Laboratories (1973) [Metasystox-R Residues in Safflower and Processed Safflower]. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-D)

00038079 Missouri Analytical Laboratories (1975) [Metasystox-R Residues in Sorghum Forage and Grain]. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-E)

00038082 Thornton, J.S.; Yoksh, R.M. (1970) Determination of Meta-Systox-R Residues in Poultry Tissues and Eggs by Thermionic Emission Flame Gas Chromatography: Report No. 27004. Method dated Mar 17, 1970. (Unpublished study including report nos. 27005, 27444, 35409..., received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-J)

00038087 Morris, R.A.; Simmons, C.E. (1975) The Effect of Processing on Metasystox-R Residues in Grapes: Report No. 43697. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:094449-Q)

00038462 Chemagro Corporation (1971) Metasystox-R Residues in Snap Beans. (Unpublished study received Mar 27, 1974 under 4F1485; CDL: 093952-B)

00038463 Chemagro Corporation (1971) Metasystox-R Residues in Lima Beans in Pod. (Unpublished study received Mar 27, 1974 under 4F1485; CDL:093952-C)

00038464 McGill, L.A. (1971) Metasystox-R Residues in Garden Peas. (Unpublished study including report no. 31441, received Mar 27, 1974 under 4F1485; prepared by Oregon State Univ., Dept. of Food Science & Technology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-D)

00038467 Thornton, J.S.; Olson, T.J. (1971) [Residues Study: Meta-Systox-R in Various Crops]: Report No. 21000. Includes method dated Oct 15, 1971. (Unpublished study including report nos. 27674, 30259 and 31443, received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-G)

00038468 Olson, T.J. (1970) A Study of the Possible Interferences of Other Pesticides with the Analytical Method for Meta-Systox-R on Crops: Report No. 21463. Rev. (Unpublished study received Mar 27, 1974 under 4F1485; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093952-H)

00044956 Nichols, S.S. (1979) Mobay Chemical Corporation--Agricultural Chemicals Division Residue Experiment: 263-1201-78D: [Metasystox-R: Report No. 67491. (Unpublished study received Jul 22, 1980 under KS 80/10; submitted by state of Kansas for Mobay Chemical Corp., Kansas City, Mo.; CDL:242969-A)

00067459 Kiigemagi, U.; Heatherbell, C.J.; Deinzer, M.L. (1979) Residues of Oxydemeton-methyl (Metasystox R) in Filberts: Report No. 67354. (Unpublished study received Jan 9, 1981 under WA 80/77; prepared by Oregon

State Univ., Dept. of Agricultural Chemistry, submitted by Washington, Dept. of Agriculture, Olympia, Wash.; CDL:CDL:244059-A)

00067474 Mobay Chemical Corporation (1979) Addition No. 4 (Lettuce), August 8, 1979, to Brochure Entitled Metasystox-R Residue Chemistry on Various Crops. (Compilation; unpublished study received Feb 21, 1980 under 3125-111; CDL:242028-A)

00068261 U.S. Department of Agriculture (1963) Results of Residue Analyses with Materials Furnished by Chemagro Corporation: Report No. 12819. (Entomology Research Div., Pesticide Chemicals Research Branch, Analytical Investigations; unpublished study; CDL:231848-A)

00070840 Mobay Chemical Corporation (1980) Addition to Synopsis of Metasystox-R Residue Chemistry on Various Fruits, Vegetables, Nuts, Field and Forage Crops. (Compilation; unpublished study received Mar 26, 1981 under 3125-111; CDL:244767-A)

00074356 Mobay Chemical Corporation (1981) Addition to Synopsis of Metasystox-R Residue Chemistry on Various Crops. (Compilation; unpublished study received Jun 9, 1981 under 3125-111; CDL:245258-A)

00074357 Thornton, J.S.; Olson, T.J. (1967) Determination of Metasystox-R Residues in Lettuce and Sugar Beets by Thermionic Emission Gas Chromatography: Report No. 21000. Method dated Oct 15, 1971. (Unpublished study received Jun 9, 1981 under 3125-111; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:245258-B)

00075902 Mobay Chemical Corporation (1966) Synopsis of Analytical and Residue Information for Meta-systox-R on Walnuts. (Compilation; unpublished study received Oct 2, 1966 under 7F0540; CDL: 090663-A)

00075903 Loeffler, W.W. (1963) Colorimetric Determination of Meta-systox-R Residues in Plant Material: Report No. 11,476. (Unpublished study received Oct 2, 1966 under 7F0540; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:090663-B)

00075906 Mobay Chemical Corporation (1965) Synopsis of Analytical, Residue, and Flavor Information for Meta-systox-R on Various Crops. (Compilation; unpublished study received Oct 2, 1966 under 7F0540; CDL:090663-I)

00090456 Mobay Chemical Corporation (1977) Metasystox-R: Residue Chemistry on Alfalfa and Clover Grown for Seed: Supplement No. 2. (Compilation; unpublished study received Oct 10, 1978 under 3125-111; CDL:235324-A)

00095522 Mobay Chemical Corporation (1963) Meta-systox-R: Analytical and Residue Information in Various Crops. Includes method dated Jun 14, 1963. (Compilation; unpublished study received Dec 30, 1963 under 3125-111; CDL:006932-A)

00095523 Mobay Chemical Corporation (1965) Synopsis of Analytical and Residue Information on Meta-systox-R in Sugar Beet Foliage. Includes method dated Jun 14, 1963. Summary of studies 006934-C through 006934-E and 090533-N. (Compilation; unpublished study received Apr 26, 1965 under 3125-111; CDL:006934-A)

00096458 Interregional Research Project Number 4 (1977) [Residue Data on Metasystox: Peaches, Lettuce, Sugar Beets]. Includes method dated Oct 15, 1971. (Compilation; unpublished study received Feb 26, 1982 under 2E2652; CDL:070706-A)

00103284 Interregional Research Project No. 4 (1977) Summary of Residue Chemistry Data. (Compilation; unpublished study received Jun 14, 1982 under 2E2710; CDL:070928-A)

00107030 Mobay Chemical Corp. (1965) [Meta-systox-R: Residues in Corn, Turnips, Cucumbers and Soil]. (Compilation; unpublished study received Aug 6, 1965 under 7F0540; CDL:090661-A)

00107031 Mobay Chemical Corp. (1966) [Meta-systox-R: Residues in Various Fruits, Vegetables, Grains, Milk and Meat]. (Compilation; unpublished study received on unknown date under 7F0540; CDL: 090662-A)

00115769 J.J. Mauget Co. (1967) [Meta-systox-R Residue Determination in Various Products]. (Compilation; unpublished study received on unknown date under unknown admin. no.; CDL:127531-A)

00116221 Shaw, H. (1975) Determination of Soil-bound Residues and Uptake by Rotational Crops from Soil Treated with Metasystox-R: Report No. 43971. Rev. (Unpublished study received Jun 18, 1975 under 5F1643; submitted by Mobay Chemical Corp., Kansas City, MO;CDL:094450-N)

00117130 Mobay Chemical Corp. (1963) Meta-systox-R: Analytical and Residue Information in Various Crops. (Compilation; unpublished study received Dec 30, 1963 under 3125-111; CDL:119843-A)

00118527 Mobay Chemical Corp. (1975) Addition No. 1 to Brochure Entitled: Metasystox-R: Residue Chemistry on Various Crops: Document No. AS76-110. (Compilation; unpublished study received Jan 28, 1976 under 3125-312; CDL:223923-A)

00120076 Mobay Chemical Corp. (1967) [Meta-Systox-R Residue on Pears and Other Crops]. (Compilation; unpublished study received Jul 18, 1968 under 8F0695; CDL:091204-D)

00120078 Mobay Chemical Corp. (1967) Meta-Systox-R: Analytical, Residue, and Flavor Information on Strawberries. (Compilation; unpublished study received Jan 8, 1968 under 8F0695; CDL:091205-A)

00120079 Mobay Chemical Corp. (1967) Meta-Systox-R: Analytical and Residue Information on Lettuce and Sugar Beets. (Compilation; unpublished study received Dec 27, 1967 under 8F0695; CDL:091206-A)

00120207 Mobay Chemical Corp. (1970) Supplement No. 1 to Brochure Entitled: Meta-systox-R: Analytical and Residue Information on Various Fruits, Vegetables, Nut, Field, and Forage Crops. (Compilation; unpublished study received on unknown date under 9F0806; CDL: 091391-A)

00120208 Mobay Chemical Corp. (1970) [Meta-Systox-R Residue on Alfalfa and Clover Grown for Seed]. (Compilation; unpublished study received Apr 29, 1969 under 9F0806; CDL:091392-A)

00120209 Mobay Chemical Corp. (1972) Supplement No. 1 to Brochure Entitled: Meta-Systox-R: Analytical and Residue Information on Alfalfa and Clover Grown for Seed. (Compilation; unpublished study received on unknown date under 9F0806; CDL:091394-A)

00124231 Mobay Chemical Corp. (1982) Metasystox-R: Residue Chemistry on Various Fruits, Vegetables, Nuts, Field and Forage Crops: Addition No. 3 (Brussels Sprouts), Brochure No. 1174: AS 83-15. (Compilation; unpublished study received Jan 13, 1983 under 3125-111; CDL:249304-A)

00135473 Mobay Chemical Corp. (1976) Addition No. 1 to Brochure Entitled: Metasystox-R: Residue Chemistry on Various Crops Dated March 14, 1975: A576-110. (Compilation; unpublished study received Jan 28, 1976 under 5F1644; CDL:098572-A)

00140798 Mobay Chemical Corporation (1970) Supplement to Synopsis of Analytical and Residue Information on Meta-systox-R in Corn, Cucumbers and Turnips: Supplement No. 1. (Compilation; unpublished study received on unknown date under 9F0806; CDL: 091393-A)

00141183 Morse Laboratories, Inc. (1981) Residues of Metasystox-R in Strawberries. Unpublished compilation. 17 p.

00152371 Mobay Chemical Corp. (1983) Metasystox-R Residues in Agricultural Crops. Unpublished compilation with analysis performed by Morse Laboratories, Inc. and Craven Laboratories, Inc. and others. 557 p.

00156398 Mobay Chemical Corp. (1985) Metasystox-R Residue Chemistry on Various Crops; Addition No. 7 (Grapes); July 12, 1985. Brochure No. 1402 to the Brochure Entitled: Metasystox-R; Analytical, Metabolic, Residue and Flavor Information on Various Crops. (Dated March 14, 1975): Report No.1402. Unpublished study. 96 p.

40404901 Smyser, B.; Halpin, R. (1987) Metabolism of Metasystox-R in Cabbage: Mobay Project ID Report No. 95012. Unpublished study prepared by Mobay Corp. 31 p.

40404902 Wagner, K.; Oehlmann, L. (1987) Studies on the Metabolic Behavior of Demeton-s-methyl in Wheat: Laboratory Project ID Report No. 95004. Unpublished study prepared by Bayer AG. 76 p.

40404903 Hawkins, D.; Kirkpatrick, D.; Till, C. (1987) Metabolism of [Carbon 14]-Metasystox-R in Sugar Beet: Project No. ID Report No. 94948. Unpublished study prepared by Huntingdon Research Centre Ltd. 72 p.

40404904 Preiss, U. (1986) Degradation of Demeton-s-methyl Sulfoxide by Cell Cultures of Tomatoes and Sugar Beets: Laboratory Project ID Report No. 94773. Unpublished study prepared by Bayer AG. 40 p.

40404905 Merricks, D. (1987) {Carbon 14}-Metasystox-R Goat Metabolism Study: Laboratory Project ID Report No. 94956. Unpublished study prepared by Agrisearch, Inc. 53 p.

40404906 Marsh, J.; Iden, B.; Lawrence, L. (1987) Quantitative Characterization of Residues in Tissues and Eggs of Laying Hens Treated Orally for Three Consecutive Days with Metasystox-R-[Carbon 14]: Laboratory Project ID Report No. 94955. Unpublished study prepared by Pharmacology and Toxicology Research Laboratory. 79 p.

40404907 Pither, K. (1987) Recovery of Metasystox-R in Animal Tissue: Laboratory Project ID Report No. 94896. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories, Inc. 179 p.

40404908 Smyser, B.; Halpin, R. (1987) Residues in Tissues and Milk of Dairy Cows Fed Metasystox-R: Laboratory Project ID Report No. 94916. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories, Inc. 78 p.

40404909 Lee, S.; Wood, S. (1987) Residue in Tissues and Eggs of Chickens Fed Metasystox-R: Report No. 94886. Unpublished study prepared by Mobay Corp. in cooperation with Harris Laboratories. 170 p.

40670001 Baron, J. (1988) Oxydemeton-methyl--Magnitude of Residue on Swiss Chard: Project ID: PR-2003. Unpublished study prepared by IR-4 Western Region Analytical Laboratory. 24 p.

41085801 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Cabbage: Project ID MS111601: Report No. 98548. Unpublished study prepared by Colorado Analytical Research and Development Corp. 40 p.

41085802 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Cabbage: Objective No. 1012: Report No. 98496. Unpublished study prepared by Colorado Analytical Research and Development Corp. 106 p.

41085806 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Green Peppers: Metasystox-R Objective No. 1822: Report No. 98549. Unpublished study prepared by Colorado Analytical Research and Development Corp. 117 p.

41085807 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Hot Peppers: Metasystox-R Objective No. 1823: Report No. 98550. Unpublished study prepared by Colorado Analytical Research and Development Corp. 70 p.

41085808 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Cantaloupes: Metasystox-R Objective No. 1310: Report No. 98551. Unpublished study prepared by Colorado Analytical Research and Development Corp. 93 p.

41085809 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Watermelon Pulp and Peel: Project ID MS111601: Report No. 98491. Unpublished study prepared by Colorado Analytical Research and Development Corp. 125 p.

41085810 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Watermelons: Metasystox-R Objective No. 1340: Report No. 98552. Unpublished study prepared by Colorado Analytical Research and Development Corp. 88 p.

41085811 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Strawberries: Project ID MS111601: Report No. 98559. Unpublished study prepared by Colorado Analytical Research and Development Corp. 71 p.

41085812 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Strawberries: Metasystox-R Objective No. 5520: Report No. 98498. Unpublished study prepared by Colorado Analytical Research and Development Corp. 109 p.

41085813 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Walnuts: Metasystox-R Objective No. 5813: Report No. 98104. Unpublished study prepared by Colorado Analytical Research and Development Corp. 62 p.

41085815 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Sweet Corn: Metasystox-R Objective Nos. 3060 & 3066: Report No. 99112. Unpublished study prepared by Colorado Analytical Research and Development Corp. 143 p.

41085819 Rhoads, W. (1989) Metasystox-R: Method Validation and Recoveries on Cottonseed: Project ID MS111601: Report No. 98488. Unpublished Corp. 55 p.

41085820 Leslie, W. (1989) Metasystox-R--Magnitude of the Residue on Cotton: Metasystox-R Objective No. 3713: Report No. 98499. Unpublished study prepared by Colorado Analytical Research and Development Corp. 120 p.

41085821 Lenz, C.; Smyser, B. (1989) Storage Stability of Metasystox-R in Frozen Cabbage: Mobay Project ID 98553. Unpublished study prepared by Colorado Analytical Research and Development Corp. 14 p.

41085822 Keatley, K. (1989) Metasystox-R and Metasystox-R-Sulphone Multiresidue Method trial: Project ID 1093: Mobay Project ID MS161-601. Unpublished study prepared by Colorado Analytical Research and Development Corp. 268 p.

41146701 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Snap Beans: Project ID 1513: Report No. 99106. Unpublished study prepared by Colorado Analytical Research and Development Corp. 111 p.

41146702 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Lima Beans: Project ID 1514: Report No. 99107. Unpublished study prepared by Colorado Analytical Research and Development Corp. 82 p.

41146703 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Field Peas: Project ID 1521: Report No. 99113. Unpublished study prepared by Colorado Analytical Research and Development Corp. 113 p.

41146704 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Field Corn: Project IDs 3064 & 3065: Report No. 99111. Unpublished study prepared by Colorado Analytical Research and Development Corp. 189 p.

41146705 Leslie, W. (1989) Metasystox-R: Method Validation and Recoveries on Alfalfa, Hay and Forage: Project ID MS111601: Report No. 98562. Unpublished study prepared by Colorado Analytical Research and Development Corp. 192 p.

41146706 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Alfalfa Project ID 3221; Report No. 99110. Unpublished study prepared by Colorado Analytical Research and Development Corp. 122 p.

41146707 Leslie, W. (1989) Metasystox-R: Magnitude of the Residue on Clover: Project ID 3222: Report No. 99109. Unpublished study prepared by Colorado Analytical Research and Development Corp. 97 p.

41247601 Leslie, W. (1989) Oxydemeton-Methyl--Magnitude of the Residue on Oranges: Project ID MS521289R01: Mobay Study No. 99636. Unpublished study prepared by Mobay Corp. 82 p.

41288901 Leslie, W. (1989) Metasystox-R Magnitude of the Residue on Corn Processed Products: Metasystox-R Project No. MS306588R02: Unpublished study prepared by Colorado Analytical Research and Development Corp. 131 p.

41288902 Leslie, W. (1989) Metasystox-R Magnitude of the Residue on Cotton Processed Products: Lab Project Number: MS371388R02. Unpublished study prepared by Colorado Analytical Research and Development Corp. 97 p.

41319001 Schmidt, B. (1989) Metasystox R--Magnitude of the Residue on Unprocessed Raw Sugar Beet and Sugar Beet Processed Products: (Mobay) 99781; Study RA-951/89; Lab Project ID R806269, etc. Unpublished study prepared by Bayer AG Versuchsgut Hoefchen, Tech. Univ. Berlin Institut fuer Zuckertechnologie and Bayer AG Pflanzenschutzzentrum Monheim. 97 p.

41514501 Schmidt, B. (1989) Metasystox-A: Magnitude of the Residue on Raw Sugar Beet and Sugar Beet Processed Products (Rev. Report): Lab Project Number: R806269: R806250. Unpublished study prepared by Bayer AG. 97 p.

41514502 Leslie, W. (1989) MetaSystox R: Magnitude of the Residue on Hot Peppers: Lab Project Number: 1823. Unpublished study prepared by Colorado Analytical Research and Development Corporation. 70 p.

44000501 Hatton, C.; Krautter, G. (1995) The Metabolism of (carbon 14)Oxydemeton-methyl in Laying Hen: Lab Project Number: 896E/506W: 896E/506W-1. Unpublished study prepared by PTRL West, Inc. and PTRL East, Inc. 263 p.

44016101 Jalali, K.; Hiler, R.; Downs, J. (1996) The Metabolism of (carbon 14)Oxydemeton-methyl in the Lactating Goat: Lab Project Number: 895E/505W: 895E/505W-1: 895. Unpublished study prepared by PTRL West, Inc. and PTRL East, Inc. 296 p.

44032501 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Cabbage Raw Agricultural Commodities: (Final Report): Lab Project Number: AA950501: 95-0037: AA950501/CA. Unpublished study prepared by American Agricultural Services, Inc and EN-CAS Analytical Labs. 249 p.

44032502 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Alfalfa Raw Agricultural Commodities: (Final Report): Lab Project Number: AA950503: 95-0039: AA950503/CA. Unpublished study prepared by American Agricultural Services, Inc. and EN-CAS Analytical Labs. 266 p.

44041101 Carringer, S. (1996) Magnitude of the Residue of Oxydemeton-Methyl + Oxydemeton-Methyl Sulfone in Sweet Corn Raw Agricultural Commodities: (Final Report): Lab Project Number: AA950502: 95-0038: 150995 PURITY AI. Unpublished study prepared by American Agricultural Services, Inc. (AASI) and EN-CAS Analytical Laboratories. 210 p.

44048201 Rose, J.; Sprinkle, R. (1996) A Metabolism Study with Oxydemeton-methyl in Cabbage: Lab Project Number: 508W: 508W-1: 895E/505W. Unpublished study prepared by PTRL West, Inc. 287 p.

44048202 Sprinkle, R.; Rose, J. (1996) A Metabolism Study with Oxydemeton-methyl in Sweet Corn: Lab Project Number: 509W: 509W-1: 895E/505W. Unpublished study prepared by PTRL West, Inc. 398 p.

44065201 Rose, J.; Sprinkle, R. (1996) A Metabolism Study with Oxydemeton-methyl in Sugarbeet: Lab Project Number: 507W-1: 507W. Unpublished study prepared by PTRL West, Inc. 302 p.

44128101 Hiler, R.; Kimmel, E.; Jalali, K. (1996) A Confined Rotational Crop Study with Oxydemeton-Methyl Using Radish, Lettuce, and Wheat: (Final Report): Lab Project Number: 511W: 95.102: 511W-1. Unpublished study prepared by PTRL WEST, Inc. and Plant Sciences, Inc. 747 p.

44228501 Jalali, K.; Hiler, R. (1997) Storage Stability of Oxydemeton-methyl and its Sulfone Metabolite in Lettuce, Sugarbeet, Sweet Corn, Broccoli, Pears, and Walnuts: Lab Project Number: 519W-1: 519W. Unpublished study prepared by PTRL West, Inc. 274 p.